

# **Temporary enhanced service specification**

## **Pertussis (pregnant women) vaccination**



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## 1 Introduction

- 1.1 All GMS practices are expected to provide essential and those additional services they have contracted to provide to all their patients. This temporary Enhanced Service (ES) specification outlines more specialised services to be provided. The specification of this ES is designed to cover the enhanced aspects of clinical care, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.
- 1.2 This ES is directed at GP practices delivering vaccination and immunisation services in England.
- 1.3 This ES is agreed between NHS Employers (on behalf of NHS England<sup>1</sup>) and the General Practitioners Committee (GPC) of the British Medical Association (BMA).

## 2 Background

- 2.1 The Chief Medical Officer (CMO), on the advice of the Joint Committee on Vaccination and Immunisation (JCVI), asked that the temporary programme of pertussis (pregnant women) vaccination be extended to respond to the ongoing outbreak of infection that led to a number of infant deaths across the country<sup>2</sup>.
- 2.2 Vaccination of pregnant women in the third trimester (recommended between 28 and 38 weeks of pregnancy) offers protection to newborns during the early weeks after birth when the risk of complications from pertussis are greatest. From 1 July 2014, the recommended vaccine for the programme changed from Repevax®<sup>3</sup> to Boostrix-IPV® (containing diphtheria, tetanus, acellular pertussis and inactivated polio antigens – dTaP/IPV). Boostrix-IPV® is licensed as a booster from aged four and contains low dose diphtheria suitable for adults.

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<sup>1</sup> From 1 April 2013 the NHS Commissioning Board (NHS CB) is the body legally responsible for the commissioning of primary care in England. However, the NHS CB operates under the name NHS England, therefore the name NHS England is used throughout this Specification.

<sup>2</sup> DH. Letter to the Service re introduction of temporary vaccination programme. September 2012. [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/212947/CMO-Pertussis-27-09-2012-FINAL.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/212947/CMO-Pertussis-27-09-2012-FINAL.pdf)

<sup>3</sup> Repevax® vaccines can be used for the pre-school booster programme.

2.3 Public Health England has secured sufficient supplies of this vaccine for this programme, which can be ordered via Immform. Further information about the immunisation programme and the change of vaccine to Boostrix-IPV® can be found in “Vaccination against pertussis (Whooping cough) for pregnant women - Information for healthcare professionals”<sup>4</sup>. Further details on background to the programme can be found in the tripartite letter dated 10 May 2013<sup>5</sup>.

2.4 Dosage and timings for the vaccination can be found in The Green Book<sup>6</sup>.

### 3 Aims

3.1 The aim of this ES is to support NHS England area teams in establishing pertussis vaccination within GP practices, in order to prevent cases of the disease and deaths in infants. Pertussis vaccination will boost immunity in women in late pregnancy so that pertussis antibodies are passed from mother to baby to passively protect infants in the first months of life (before they receive their routine childhood immunisations from aged two months). It is important for all women to be offered the pertussis vaccine during each pregnancy.

3.2 Since this temporary ES was introduced in 2012 uptake levels have been similar to that of influenza vaccination in pregnant women and it is envisaged that this will continue to be the case. There should be no detriment to routine childhood vaccination uptake as a consequence of this additional programme.

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<sup>4</sup> Vaccination against pertussis (whooping cough) for pregnant women.  
<https://www.gov.uk/government/publications/vaccination-against-pertussis-whooping-cough-for-pregnant-women>

<sup>5</sup> DH. Letter to the Service re extension of temporary vaccination programme. May 2013.  
[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/197839/130510\\_Pertussis\\_continuation\\_letter\\_FINAL.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/197839/130510_Pertussis_continuation_letter_FINAL.pdf)

<sup>6</sup> DH. Green Book. <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

## 4 Process

- 4.1 This ES was introduced on 1 October 2012 for as long as the temporary programme continued to be advised by the CMO. The programme's impact continues to be reviewed by the CMO.
- 4.2 This ES will apply for the period from 1 April 2014 until 31 March 2015. Thereafter a decision will be made as to whether it is appropriate to cease or continue the programme.
- 4.3 NHS England area teams will offer this ES to GP practices.
- 4.4 NHS England area teams will seek to invite and sign up GP practices to participate in this ES by no later than 30 June 2014.

## 5 Service specification

- 5.1 The requirements for GP practices participating in the ES are as follows:
  - i. **Offer and (where accepted) provide pertussis vaccination to all pregnant women on the contractor's patient list for whom immunisation is recommended.** That is, all pregnant women who reach or were already at the 28th week of their pregnancy from 1 April 2014 to 31 March 2015 unless immunisation is contra-indicated. Immunisation is contra-indicated where the patient has previously had a confirmed anaphylactic reaction to a previous dose of the vaccine, or to any component of the vaccine.

The contractor is expected to offer vaccination before week 38 of pregnancy. The optimal time is in the period weeks 28 to 32 inclusive to maximise transplacental transfer of antibodies to the unborn child. Pregnant women who miss vaccination and are beyond week 38 of pregnancy should be offered immunisation up to the onset of labour so that some direct protection may still be provided to the infant.

**Contractors may also offer vaccination to new mothers (up to two months after the birth of the baby) who missed the opportunity to be vaccinated during pregnancy to reduce the risk of the mother contracting pertussis in the post-partum period and therefore prevent her from infecting her infant.**

- ii. Produce and maintain a satisfactory register of all eligible pregnant women** on the contractor's registered list during each financial year of the programme. Simple registers of pregnant women are all that is required, although these will need to be updated regularly to capture the target population and record the estimated due date (EDD) so it is known when they are eligible for vaccination.
- iii. GP practices will need to decide on the best mechanisms to contact all eligible pregnant women on the contractor's register to maximise uptake.** They will particularly need to consider how to contact women who are solely in the care of a midwife or hospital consultant.
- iv. Liaise with and inform all eligible pregnant women of the benefits of being immunised** and making full use of all publicity and information materials available for national/local campaigns. Health professionals should ensure that appropriate information and advice about the pertussis vaccine is given to each pregnant woman who attends an immunisation session and be given reasonable opportunity to discuss any concerns before being immunised.
- v. Take all reasonable steps to ensure that the medical records of patients receiving the pertussis immunisation are kept up to date with regard to the immunisation status** and in particular, include:
  - a.** any refusal of an offer of immunisation.
  - b.** where an offer of immunisation was accepted:

- i. details of the consent to the immunisation (including persons that have consented on the patient's behalf and that person's relationship to the patient must also be recorded),
  - ii. the batch number, expiry date and title of the vaccine,
  - iii. the date of administration,
  - iv. where two vaccines are administered in close succession (for example, pertussis and influenza) , the route of administration and the injection site of each vaccine,
  - v. any contra-indication to the vaccination or immunisation,
  - vi. any adverse reactions to the vaccination or immunisation.
- vi. **Ensure that all healthcare professionals who are involved in administering the vaccine have:**
  - a. referred to the clinical guidance in the CMO letter of 27 September 2012<sup>7</sup>,
  - b. the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.
- vii. **Ensure that all vaccines ordering is conducted in line with national guidance**, including adherence to any limits on stocks to be held at any one time. The vaccine currently advised for this programme is dTaP/IPV (Repevax®/Boostrix-IPV®) as currently used in the routine childhood programme. This vaccine will be supplied centrally, ordered from ImmForm as per other centrally supplied vaccines.
- viii. **Ensure that all vaccines are stored in accordance with the manufacturer's instructions** and that all refrigerators in which vaccines

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<sup>7</sup> DH. Letter to the Service re introduction of temporary vaccination programme. September 2012. <https://www.gov.uk/government/publications/whooping-cough-vaccination-programme-for-pregnant-women>

are stored have a maximum/minimum thermometer and that the readings are taken and recorded from that thermometer on all working days.

- ix. **Services will be accessible, appropriate and sensitive to the needs of all service users.** No eligible patient shall be excluded or experience particular difficulty in accessing and effectively using this ES due to their race, gender, disability, sexual orientation, religion and/or age.
  
- x. **Providers will monitor and report activity information via ImmForm on a monthly basis.** The activity information shall include:
  - a. a denominator " Number of Pregnant Patients (28 weeks and over) and number of new mothers (during two months after birth) " which is the count of all pregnant women on the contractor's register who reach or were already at the 28th week of their pregnancy from the 1 April 2014, updated periodically and all new mothers who were administered the vaccine during the first two months after the baby's birth.
  
  - b. a numerator "Number Vaccinated with Repevax®/Boostrix-IPV®" which is the count of all those within the denominator that were vaccinated with Repevax®/Boostrix-IPV®. Women who reach or were already at the 28th week of their pregnancy but were no longer pregnant by the time a vaccination was arranged should still be included in the denominator, as they were eligible at some point in time.

## 6 Monitoring

- 6.1 NHS England through area teams will monitor services and calculate payments under this ES. Payments are anticipated to be made from July 2014 after GP practices have confirmed their participation in this ES in line with paragraph 4.4. This ES is not supported by GPES or CQRS. Practices and area teams must agree a local arrangement for reporting and payment of this ES.

## 7 Payment and validation

7.1 Payment available to participating GP practices under this ES in 2014/15 is priced as follows:

- Pertussis vaccinations for pregnant women is £7.67 per patient.
- Pertussis vaccinations for new mothers is £7.67 per patient.

7.2 As the vaccine is centrally supplied, no claim for reimbursement of vaccines costs or a personal administration fee apply.

7.3 Administrative provisions relating to payments under this ES are set out in the Annex.

# Annex. Administrative provisions relating to payments under the temporary enhanced service for pertussis (pregnant women) vaccination

1. Payments under this ES are to be treated for accounting and superannuation purposes as gross income of the GP practice in the financial year.
2. The amount calculated as payment for the financial year falls due on the last day of the month following the month during which the GP practice provides the information specified in this specification or as agreed with area teams.
3. Payment under this ES, or any part thereof, will be made only if the GP practice satisfies the following conditions:
  - the GP practice must make available to NHS England any information under this ES, which NHS England needs and the GP practice either has or could be reasonably expected to obtain,
  - the GP practice must make any returns required of it (whether computerised or otherwise) to the Exeter Registration System or CQRS, and do so promptly and fully; and,
  - all information supplied pursuant to or in accordance with this paragraph must be accurate.
4. If the GP practice does not satisfy any of the above conditions, NHS England may, in appropriate circumstances, withhold payment of any, or any part of, an amount due under this ES that is otherwise payable.
5. If NHS England makes a payment to a GP practice under this ES and:
  - the contractor was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment or because the payment was calculated incorrectly (including where a payment on account overestimates the amount that is to fall due);
  - NHS England was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or
  - NHS England is entitled to repayment of all or part of the money paid,

NHS England may recover the money paid by deducting an equivalent amount from any payment payable to the GP practice, and where no such deduction can be made, it is a condition of the payments made under this ES that the contractor must pay to NHS England that equivalent amount.

6. Where the NHS England is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition, and NHS England does so or recovers the money by deducting an equivalent amount from another payment in accordance with paragraph 5, it may, where it sees fit to do so, reimburse the contractor the amount withheld or recovered, if the breach is cured.

### **Provisions relating to GP practices that terminate or withdraw from this ES prior to 31 March 2015 (subject to the provisions below for termination attributable to a GP practice split or merger)**

7. Where a GP practice has entered into this ES but its primary medical care contract subsequently terminates or the GP practice withdraws from the ES prior to 31 March 2015, the GP practice is entitled to a payment in respect of its participation if such a payment has not already been made, calculated in accordance with the provisions set out below. Any payment calculated will fall due on the last day of the month following the month during which the GP practice provides the information required.
8. In order to qualify for payment in respect of participation under this ES, the GP practice must provide NHS England area teams with the information in this ES specification or as agreed with area teams before payment will be made. This information should be provided in writing, within 28 days following the termination of the contract or the withdrawal from the ES agreement.
9. The payment due to GP practices that terminate or withdraw from the ES prior to 31 March 2015 will be based on the number of vaccination given, prior to the termination or withdrawal.

### **Provisions relating to GP practices who merge or split**

10. Where two or more GP practices merge or are formed following a contractual split of a single GP practice and as a result the registered population is combined or divided between new GP practice(s), the new GP practice(s) may enter into a new agreement to provide this ES.
11. The ES agreements of the GP practices that formed following a contractual merger, or the GP practice prior to contractual split, will be treated as having terminated and the entitlement of those GP practice(s) to any payment will be assessed on the basis of the provisions of paragraph 7 of this annex.
12. The entitlement to any payment(s) of the GP practice(s), formed following a contractual merger or split, entering into this ES will be assessed and any new arrangements that may be agreed in writing with the NHS England will commence at the time the GP practice(s) starts to provide such arrangements.

13. Where that agreement is entered into and the arrangements commence within 28 days of the new GP practice(s) being formed, the new arrangements are deemed to have commenced on the date of the new GP practice(s) being formed. Payment will be assessed in line with this ES service specification as of this commencement date.

## **Provisions relating to non-standard splits and mergers**

14. Where the GP practice participating in the ES is subject to a split or a merger and:

- the application of the provisions set out above in respect of splits or mergers would, in the reasonable opinion of NHS England, lead to an inequitable result; or,
- the circumstances of the split or merger are such that the provisions set out in this section cannot be applied,

NHS England may, in consultation with the GP practice or GP practices concerned, agree to such payments as in NHS England's opinion are reasonable in all circumstances.